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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,890	04/28/2000	ULRICH H. KOSZINOWSKI	203640	6925

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/463,890	Applicant(s) KOSZINOWSKI ET AL.	
	Examiner Daniel M. Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005 and 30 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,37 and 40-72 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,37,40-44,46-48,50,51,53,54,56-64 and 67-72 is/are rejected.
- 7) ☒ Claim(s) 45,49,52,55,65 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Papers filed 1 September 2005 and 30 December 2005 in response to the Non-Final Office Action mailed 3 March 2005. Claims 36-72 were considered in the 3 March Office Action. Claims 38 and 39 were canceled and claims 36, 40, 63, 64, 68 and 71 were amended in the 30 December Paper. Claims 36, 37 and 40-72 are pending and under consideration.

Priority

In the 3 March Office Action (page 3) Applicant was notified that in order to obtain benefit of the filing date of the foreign application, applicants must submit a certified translation of the priority document. 37 CFR §1.55(a)(4)(ii) states, "If an English language translation is required, it must be filed together with a statement that the translation of the certified copy is accurate." Applicant's submission contains no such statement and is, therefore, insufficient.

Response to Amendment and Arguments

Rejection of claims 38 and 39 is rendered moot by the cancellation thereof.

Sequence Compliance

The submission filed 1 September 2005 is not fully compliant with the requirements of 37 CFR 1.821 through 1.825. Specifically, the submission does not include a statement directing entry of the paper copy of the sequence listing into the specification. Applicant's response to this

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Office Action should include as statement referring to the sequence listing filed 1 September 2005 and properly directing its entry into the specification.

Drawings

The substitute sheet of drawings filed 1 September 2005 has been entered

Claim Rejections - 35 USC § 112

Rejection of claims 40-44, 63-64 & 71-72 under 35 U.S.C. 112, second paragraph, as being indefinite is **withdrawn** in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

Claims 36, 37, 40-43, 46-48, 50-51, 53-54, 56-64 & 67-72 stand rejected under 35 U.S.C. 102(a) as being anticipated by Messerle et al (PNAS USA, December 1997, Vol. 9, pages 14759-14763; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 6. In response to the *prima facie* rejection of record, Applicant contends that the reference does not apply in view of the filing of a translation of the priority document. However, as discussed above, the submission is not compliant with the requirements of 37 CFR §1.55 and, therefore, is insufficient to overcome the rejection of record.

Claims 36, 48, 51, 54, 57-60, 63-64, 67-69 & 71 stand rejected under 35 U.S.C. 102(e) as being anticipated by Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see

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the entire patent) for the reasons set forth in the 3 March Office Action commencing at page 7. In response to the *prima facie* rejection of record, Applicant contends that the reference does not apply in view of the filing of a translation of the priority document. However, as discussed above, the submission is not compliant with the requirements of 37 CFR §1.55 and, therefore, is insufficient to overcome the rejection of record.

Claims 36, 43, 48, 51, 54, 57-60 & 63 **stand rejected** under 35 U.S.C. 102(a) as being anticipated by Delecluse et al (Proceedings of the National Academy of Sciences, USA. 7 July 1998, Vol. 95, pages 8245-8250; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 9. In response to the *prima facie* rejection of record, Applicant contends that the reference does not apply in view of the filing of a translation of the priority document. However, as discussed above, the submission is not compliant with the requirements of 37 CFR §1.55 and, therefore, is insufficient to overcome the rejection of record.

Claims 71-72 **stand rejected** under 35 U.S.C. 102(b) as being anticipated by Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 9 and herein below in the response to Applicant arguments.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant contends that the reference does not apply because Messerle et al. does not teach using a bacterial host cell that contains mutagenizing DNA molecules to produce BAC/MCMV hybrid molecules.

This argument has been fully considered but is not deemed persuasive. Applicant is reminded that the invention of claims 71 and 72 is a product made by the process of claim 67, wherein the process is open (*i.e.*, comprises the recited steps and any additional step). Furthermore, as the claims are product-by-process, they read on the product made by any means. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”

As stated in the 3 March Office Action, page 10, “claim 71 can reasonably be interpreted broadly to encompass any BAC vector that comprises any mutated sequence from a virus having a genome of greater than 100 kb and which could be obtained by the claimed method (e.g. the BAC/CMV constructs taught by Messerle et al). As currently written, the rejected claims do not specify any structural/functional characteristic that is necessarily conveyed to the claimed recombinant vector by the method of mutagenesis recited in claim 67” (emphasis in original). Although claim 71 has been amended to recite that the recombinant vector contains a mutagenized viral genomic sequence larger than 100 kb, the recombinant vector of Messerle et

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al. also comprises a mutagenized viral genomic sequence larger than 100kb (see the sentence bridging pages 9-10 of the 3 March Office Action). Thus, the recombinant vector of Messerle et al. is the same as the recombinant vector of the instant claims.

Claim 71 **stands rejected** under 35 U.S.C. 102(b) as being anticipated by Luckow et al (Journal of Virology, 1993, Vol. 67, No. 8, pages 4566-4579; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 10 and herein below in the response to Applicant arguments.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant contends that the reference does not apply because Luckow et al. does not teach a recombinant vector containing an infectious herpes virus genomic sequence larger than 100kb and all or a portion of a BAC. This argument has been fully considered but is not deemed persuasive because, as discussed above, the rejected claim is directed to a product made by a process of mutagenesis comprising unlimited steps. The fact that the starting material used in the process is different from the product disclosed in Luckow et al. is immaterial because what is claimed is the product of the process. In other words, the vector of Luckow *et al.* could be produced by the method of claim 67 given the process steps explicitly recited in the claim and sufficient additional process steps, which are also encompassed by the process of claim 67. As the only structural characteristic required to meet the limitations of claim 71 is that the recombinant vector contain a mutagenized viral genomic sequence larger than 100 kb and Luckow et al. teaches a mutagenized viral

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genomic sequence of ~130 kb (page 11 of the 3 March Office Action), the recombinant vector of Luckow et al. is the same as the recombinant vector of the instant claims.

Claim Rejections - 35 USC § 103

Claims 37, 40-43 & 72 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent) in view of Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996; see the entire reference) for the reasons set forth in the 3 March Office Action commencing at page 12 and herein below in the response to Applicant arguments.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant contends that the art does not apply because the '621 patent is antedated in view of the filing of a translation of the foreign priority documents and because Messerle et al. does not teach using a bacterial host cell that contains mutagenizing DNA molecules to produce BAC/MCMV hybrid molecules.

However, as discussed above, the submission of the translation is not compliant with the requirements of 37 CFR §1.55 and, given the broadest reasonable interpretation of a product made by the recited process, the structural properties of the product of claim 72 are not different from the product disclosed in Messerle et al.

New Grounds Necessitated by Amendment

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in depending from a cancelled claim (i.e., claim 39). As the claims depend from a claim that is no longer pending in the application, the metes and bounds of the claimed subject matter are indeterminable.

Allowable Subject Matter

Claims 45, 49, 52, 55, 65 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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DANIEL M. SULLIVAN
PATENT EXAMINER